

REMARKS

Amendments

Claims 1-40 have been canceled, and claims 41-46 have been added. Upon entry of the amendment, claims 41-46 will be pending. Support for the added claims can be found in the specification; page 7, lines 28-31; Figure 2; and in the claims as originally filed. The specification has been amended to update application information.

The foregoing amendments are made solely to expedite prosecution of the application and are not intended to limit the scope of the invention. Further, the amendments to the claims are made without prejudice to the pending or now canceled claims or to any subject matter pursued in a related application. The Applicant reserves the right to prosecute any canceled subject matter at a later time or in a later filed divisional, continuation, or continuation-in-part application.

Objections

Table 1 has been objected to as allegedly being inconsistent with the specification. While Applicant maintains its position set forth in previous responses, the Table has been amended for the purpose of expediting prosecution.

Rejections

Rejections under 35 U.S.C. § 101

The Examiner has rejected claims 30-33, 35-37, 39 and 40 because the claimed invention is allegedly not supported by either a specific or substantial asserted utility or a well-established utility.

Applicant respectfully traverses the rejection. New claim 41 is drawn to a transgenic mouse having a null ubiquitin ligase E3 allele, wherein the allele comprises the sequence of SEQ ID NO:1; and the null allele comprises exogenous DNA comprising a selection marker and a visible marker. According to 35 U.S.C. § 101, “[w]hoever invents . . . any new and useful . . . composition of matter may obtain a patent therefore. . . .”

Under the Patent Office’s Utility Requirement Guidelines:

If at any time during the examination, it becomes readily apparent that the claimed invention has a well-established utility, do not impose a rejection based on lack of utility. An invention has a well-established utility if (i) a person of

ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible.

...

If the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a “specific and substantial utility”) and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility.

(emphasis added)(MPEP § 2107, II (A)(3); II (B)(1)). Thus, according to Patent Office guidelines, a rejection for lack of utility may not be imposed where an invention has a well-established utility or is useful for any particular practical purpose. The present invention satisfies either standard.

The present invention has a well-established utility since a person of ordinary skill in the art “would immediately appreciate why” knockout mice are useful. As a general principle, any knockout mouse has the inherent and well-established utility of defining the function and role of the disrupted target gene, regardless of whether the inventor has described any specific phenotypes, characterizations or properties of the knockout mouse. The sequencing of the human genome has produced countless genes whose function has yet to be determined. According to the National Institute of Health, knockout mice represent a critical tool in studying gene function:

Over the past century, the mouse has developed into the premier mammalian model system for genetic research. Scientists from a wide range of biomedical fields have gravitated to the mouse because of its close genetic and physiological similarities to humans, as well as the ease with which its genome can be manipulated and analyzed.

...

In recent decades, researchers have utilized an array of innovative genetic technologies to produce custom-made mouse models for a wide array of specific diseases, as well as to study the function of targeted genes. One of the most important advances has been the ability to create transgenic mice, in which a new gene is inserted into the animal's germline. Even more powerful approaches, dependent on homologous recombination, have permitted the development of tools to “knock out” genes, which involves replacing existing genes with altered versions; or to “knock in” genes, which involves altering a mouse gene in its natural location. To preserve these extremely valuable strains of mice and to

assist in the propagation of strains with poor reproduction, researchers have taken advantage of state-of-the-art reproductive technologies, including cryopreservation of embryos, in vitro fertilization and ovary transplantation.

(<http://www.genome.gov/pfv.cfm?pageid=10005834>) (emphasis added). Thus, the knockout mouse has been accepted by the NIH as the premier model for determining gene function, a utility that is specific, substantial and credible.

Knockout mice may be used as research tools, with respect to which the Patent Office has commented:

Some confusion can result when one attempts to label certain types of inventions as not being capable of having a specific and substantial utility based on the setting in which the invention is to be used. One example is inventions to be used in a research or laboratory setting. Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific and unquestionable utility (e.g., they are useful in analyzing compounds). An assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the invention is in fact “useful” in a patent sense. Instead, Office personnel must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm. Labels such as “research tool,” “intermediate” or “for research purposes” are not helpful in determining if an applicant has identified a specific and substantial utility for the invention.

(MPEP § 2107.01, I). As with gas chromatographs, screening assays and nucleotide sequencing techniques, knockout mice have a clear, specific and unquestionable utility (e.g., they are useful in analyzing gene function).

According to the Molecular Biology of the Cell (Albert, 4th ed., Garland Science (2002)), one of the leading textbooks in the field of molecular biology:

Extensive collaborative efforts are underway to generate comprehensive libraries of mutation in several model organisms including . . . the mouse. The ultimate goal in each case is to produce a collection of mutant strains in which every gene in the organism has either been systematically deleted, or altered such that it can be conditionally disrupted. Collections of this type will provide an invaluable tool for investigating gene function on a genomic scale.

(p. 543)(emphasis added).

In addition, commercial use and acceptance is one important indication that the utility of an invention has been recognized by one of skill in the art (“A patent system must be related to

the world of commerce rather than to the realm of philosophy.” *Brenner v Manson*, 383 U.S. 519, 148 U.S.P.Q. 689, 696 (1966)). Commercial use of the knockout mice produced by Assignee Deltagen has been clearly established. The presently claimed transgenic mouse has been specifically ordered, bred and delivered to at least one customer for the purpose of studying the function of the target gene. This should more than satisfy the practical utility requirement of section 101 as it cannot be reasonably argued that a claimed invention which is actually being used has no use.

Applicant submits that since one of ordinary skill in the art would immediately recognize the utility of a knockout mouse in studying gene function, a utility which is specific, substantial and credible, the invention has a well-established utility, thus satisfying the utility requirement of section 101. On this basis alone, withdrawal of the rejection with respect to the present invention is warranted, and respectfully requested.

In addition, the claimed invention is useful for a particular purpose. The genomes of the heterozygous mice contain a lacZ reporter gene. The mice are useful for studying expression profiles of the ubiquitin ligase E3 gene, a utility which would be considered credible by one skilled in the art.

In summary, Applicant submits that the claimed transgenic mouse, regardless of any disclosed phenotypes, has inherent and well-established utility in the study of the function of the gene, and thus satisfies the utility requirement of section 101. Moreover, Applicant believes that the transgenic mice are useful for studying ubiquitin ligase E3 gene expression and are therefore useful for a specific practical purpose that would be readily understood by and considered credible by one of ordinary skill in the art.

In light of the arguments set forth above, Applicant does not believe that the Examiner has properly established a *prima facie* showing that establishes that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the Applicant would be specific and substantial. (*In re Brana*; MPEP § 2107). Withdrawal of the rejections is respectfully requested.

Rejections under 35 U.S.C. § 112, 1st paragraph

Claims 1 and 20-24 stand rejected for lack of enablement. Applicant traverses the rejection. As argued above, the claimed invention satisfies the utility requirement, therefore, one

skilled in the art would know how to use the invention. Withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 112, 2nd paragraph

Claims 39 and 40 have been rejected as being indefinite. The claims have been canceled rendering the rejection moot. Withdrawal of the rejection is respectfully requested.

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-1271 under Order No. R-441.

Respectfully submitted,

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